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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,914	05/02/2001	Y. Tom Tang	PF-0621 USN	5287

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EXAMINER
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ART UNIT	PAPER NUMBER
1652	19

DATE MAILED: 04/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/830,914	Tang et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above, claim(s) *1, 2, 7, 8, and 15-20* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *3-6 and 9-14* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *May 2, 2001* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 2, and 15, drawn to a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and fragments thereof.

Group II, claims 3-6 and 9-14, drawn to a polynucleotide, vector, host cell, and method for producing a polypeptide.

Group III, claims 7 and 8, drawn to a method for detecting a polynucleotide by hybridizing a polynucleotide to a sample.

Group IV, claim 16, drawn to an antibody which specifically binds to a polypeptide.

Group V, claim 17, drawn to a purified agonist of a polypeptide.

Group VI, claim 18, drawn to a purified antagonist of a polypeptide.

Group VII , claim 19, drawn to a method for treating or preventing a disorder associated with decreased expression or activity of MHCH by administering an effective amount of a pharmaceutical composition comprising a polypeptide.

Group VIII, claim 20, drawn to a method for treating or preventing a disorder associated with decreased expression or activity of MHCH by administering an effective amount of an antagonist.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of the inventions listed as Groups I-VII is a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and fragments thereof. However, Kinkema et al. (Accession Q39157) teach a myosin heavy chain polypeptide comprising a fragment of SEQ ID NO: 1 (see attached alignment).

Since Applicants have not contributed a special technical feature over the prior art, Groups I-VIII do not have a single general inventive concept and therefore lack unity of invention.

3. During a telephone conversation with Diana Hamlet-Cox on March 27, 2003 a

provisional election was made with traverse to prosecute the invention of Group II, claim claims 3-6 and 9-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1, 2, 7, 8, and 15-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Claims 3-6 and 9-14 are under consideration in this Office Action.

Claim Objections

6. Claims 3-6 are objected to because they depend from nonelected claim 1. Applicants are required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. For examination purposes, it is assumed that claims 3-6 recite all the limitations of claim 1.

7. Claims 4 and 10 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claim(s) in independent form. The claims expand the scope of claim 3 and claim 9, respectively.

Claim Rejections - 35 U.S.C. § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 3-6 and 9-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants disclose the nucleotide sequences of SEQ ID NO: 2 and the deduced amino acid sequence of SEQ ID NO: 1. Applicants disclose that based on homology searches that the

protein of SEQ ID NO: 1 is a "new human myosin heavy chain homolog (MHCH)" which is a generic asserted utility. The specification does not specifically disclose the specific function of the protein of SEQ ID NO: 2 or its specific relationship to any disease. It appears that the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and possible diseases associated with the protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 3-6 and 9-14 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 3-6 and 9-14 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, claims 3, 4, 9, 10 which encompass any polynucleotide of any nucleotide sequence having 70% identity to any polynucleotide encoding SEQ ID NO: 1 or any fragment thereof or any polynucleotide having 70% identity to SEQ ID NO: 2 or any fragment thereof are not enabled by the specification.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any polynucleotide of any nucleotide sequence having 70% identity to any polynucleotide encoding SEQ ID NO: 1 or any fragment thereof or any polynucleotide having 70% identity to SEQ ID NO: 2 or any fragment thereof

The specification provides guidance and examples for making an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 1 or an isolated polynucleotide comprising SEQ ID NO: 2. However, the specification does not teach the

specific structural/catalytic amino acids and the structural motifs essential for protein activity/function which cannot be altered. The state of the art as exemplified by Attwood et al. (Comput. Chem. 2001, Vol. 25(4), pp. 329-39) is such that "...we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given knowledge only of its sequence or structure in isolation" (see Abstract and entire publication). Furthermore, Ponting (Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29) states that "...predicting function by homology is a qualitative, rather than quantitative, process and requires particular care to be taken...due attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domains in proteins" (See Abstract and entire publication).

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed polynucleotide is enormous and entails selecting specific nucleotides to change (deletion, insertion, substitution, or combinations thereof) in a polynucleotide to make any polynucleotide of any nucleotide sequence having 70% identity to any polynucleotide encoding SEQ ID NO: 1 or any fragment thereof or any polynucleotide having 70% identity to SEQ ID NO: 2 or any fragment thereof and determining by assays whether the polypeptide has activity. The specification does not provide guidance with respect to the specific structural/catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved. Thus, searching for the specific nucleotides to change (deletion, insertion, substitution, or combinations thereof) in a polynucleotide to make any polynucleotide of any nucleotide sequence having 70% identity to any polynucleotide encoding SEQ ID NO: 1 or any fragment thereof or any polynucleotide having 70% identity to SEQ ID NO: 2 or any fragment thereof is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polypeptide has activity is extremely low since no information is provided by the specification regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific catalytic amino acids and the structural motifs essential for activity/function which must be preserved. Without such a guidance, the experimentation left to those skilled in the art is undue.

12. Claims 3-6 and 9-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to any polynucleotide of any nucleotide sequence having 70% identity to any polynucleotide encoding SEQ ID NO: 1 or any fragment thereof or any

polynucleotide having 70% identity to SEQ ID NO: 2 or any fragment thereof.

The specification, however, only provides the following representative species encompassed by these claims: a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 2 and a polynucleotide encoding a polypeptide consisting of the amino acid sequence SEQ ID NO: 1. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is vague and indefinite because the specific nucleotide sequence of the polynucleotide to which the claimed polynucleotide has 70% identity to is not known and not stated in the claim. Amending the claim to recite that the polynucleotide encodes a polypeptide that has an amino acid sequence that is 90% identical to SEQ ID NO: 1 may overcome the rejection.

Claim 5 is vague and indefinite because the "specific stringent conditions" are not known and not recited in the claim.

Claim Rejections - 35 U.S.C. § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use

or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claim 3 is rejected under 35 U.S.C. 102(a) as being anticipated by Calabretta et al. (US Patent 5,734,039).

Calabretta et al. (US Patent 5,734,039) teach a polynucleotide that encodes a fragment of the polypeptide comprising SEQ ID NO: 1 (see attached alignment). Thus, the reference teachings anticipate the claimed invention.

17. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Dahlberg et al. (US Patent 5,541,311).

Dahlberg et al. (US Patent 5,541,311) teach a polynucleotide that comprises a fragment of the nucleotide sequence SEQ ID NO: 2 (see attached alignment). Thus, the reference teachings anticipate the claimed invention.

Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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